REMARKS

In response to the Office Action dated November 20, 2006, Applicants submit the following remarks.

The three-month extended deadline for filing a response falls on May 20, 2007. A three-month Petition for Extension of Time and the required fee are filed herewith; therefore, Applicants believe that this response is being timely filed. In the event that there are any additional fees required in connection with this response, please charge any necessary fee to Deposit Account No. 23-2415, referencing Docket No. 30797-717.201.

Claim 3 was previously canceled, and claims 8-11 and 19 have been canceled herein. Applicants have canceled claims solely to further prosecution and reserve the right to pursue any canceled subject matter in continuing and/or divisional applications.

Claims 1, 4, 5, 6, 7, 12, 14 and 18 have been amended to recite a "composition" rather than a "vaccine composition" solely to further prosecution. Support for such amendments can be found throughout the specification and claims as filed and do not add new matter. The compositions described and claimed herein induce immune responses such as, for example, induction of antibody responses. Such immune responses are characteristics of cancer vaccines. Thus, the cancellation of the claims is not to be considered as acquiescence to the rejections of record.

Claims 4, 5 and 6 have been amended to recite a "nucleic acid sequence encoding said fusion protein." Support for such amendments can be found in throughout the Examples of the specification in which nucleic acid sequences were combined to encode fusion proteins. Thus, the claim amendments do not add new matter.

Withdrawn claims 14-18 have been amended similarly to the composition claims and, as such, do not add any new matter. Applicants submit that the claims as currently recited are allowable and request rejoinder of withdrawn method claims 14-18 which have been amended to be consistent with the composition claims in accordance with *In re Ochiai* 71 F.3d 1565, 37

USPQ2d 1127 (Fed. Cir. 1995); and *In re Broewer* 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996).

In view of the remarks and amendments submitted herein, Applicants believe that the Application is in condition for allowance and such favorable action is earnestly solicited.

By the above amendments, Applicants have amended the claims to expedite prosecution of the subject application. However, Applicants reserve the right to resubmit the canceled subject matter in one or more continuation applications without prejudice.

Applicants acknowledge withdrawal of the following objections and rejections:

1. The rejection of claims 1 and 2 under 35 USC 102(b) as being allegedly anticipated by either Heimbrook or Kunwar as evidenced by Chaudhary;
2. The objection to claims 1, 2, 4, 5 and 7-11 because of the term TGFα instead of human TGFα or hTGFα;
3. The objection to the specification for not being in compliance with the sequence rules;
4. The rejection of claims 1 and 2 under 35 USC 102(b) as being allegedly anticipated by Hoeprich.

The Examiner has maintained the following claim rejections:

1. The Examiner has maintained the rejection of claims 8, 9, 10 and 11 under 35 U.S.C. § 112, first paragraph as allegedly not being enabled over the full scope of the claims with respect to "EGF."

Applicants maintain for the reasons of record that Applicants are not required to reproduce in the specification what is known in the art. However, solely in an effort to further prosecution, Applicants have canceled claims 8, 9, 10 and 11, thereby rendering the rejection moot. Applicants reserve the right to resubmit the canceled subject matter in one or more

continuation and/or divisional applications without prejudice and respectfully request withdrawal of the rejection.

2. The Examiner has maintained the rejection of claims 8, 9, 10 and 11 under 35 U.S.C. § 112, first paragraph as allegedly lacking written description with respect to "EGF."

Applicants maintain for the reasons of record that Applicants are not required to reproduce in the specification what is known in the art. However, solely in an effort to further prosecution, Applicants have canceled claims 8, 9, 10 and 11, thereby rendering the rejection moot. Applicants reserve the right to resubmit the canceled subject matter in one or more continuation and/or divisional applications without prejudice and respectfully request withdrawal of the rejection.

3. Claims 1-13 remain provisionally rejected under the judicially created doctrine of obviousness- type double patenting as allegedly being unpatentable over Claims 7, 10, 11, 12, 23 and 26 of Application No. 10/005,341.

Applicants respectfully point out that U.S. Application No. 10/005,341 was abandoned on June 2, 2006, and submit that the applications are no longer co-pending. Consequently, Applicants respectfully request reconsideration and withdrawal of the rejection.

New Grounds of Rejection

4. Claims 1, 2 and 4-13 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

a. Claim 1 is allegedly indefinite because it contains a reference to any carrier protein and then "said protein." The Examiner stated that the rejection could be overcome by amending claim 1 to recite "a carrier protein" instead of "any carrier protein."

Applicants have amended claim 1 as suggested by the Examiner and respectfully request reconsideration and withdrawal of the rejection.

b. Claims 10 and 11 are allegedly indefinite because they are both drawn to compositions comprising a mix of two vaccine preparations.

Applicants submit that the rejection of claims 10 and 11 is moot in light of the cancellation of these claims and respectfully request reconsideration and withdrawal of the rejection.

c. Claims 4, 5 and 6 are allegedly indefinite because of the recitation of the term "gene."

Applicants have amended claims 4, 5 and 6 to recite nucleic acid sequences that encode the fusion proteins; support for such amendments can be found throughout the Examples of the specification in which nucleic acid sequences were combined to encode fusion proteins. Thus, the claim amendments do not add new matter and Applicants respectfully request reconsideration and withdrawal of the rejection.

5. Claims 1, 2 and 4-13 are rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking enablement for the full scope of the claims.

The Examiner states at page 7 of the Office Action that "the specification does not reasonably provide enablement for vaccines comprising human TGFα linked to P64 either by chemical means or as a fusion protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most reasonably connected, to use the invention commensurate in scope with these claims. The basis for this rejection is that the specification fails to enable one of skill in the art to use the claimed compositions as prophylactic cancer vaccines for the intended use of preventing cancer."

The Examiner states at page 9 of the Office Action that the "rejection would be overcome if the claims are amended to be drawn to "compositions" instead of "vaccine compositions.'

Applicants respectively disagree with the Examiner's statements for the reasons of record. Briefly, the art to which the claims pertain is cancer therapy. In the field of cancer therapy, "vaccine compositions" are compositions that induce an immune response as seen in many publications in the field and as shown by induction of antibody responses in the present application. Nonetheless, solely in an effort to further prosecution, Applicants have amended the claims as suggested by the Examiner and respectfully request reconsideration and withdrawal of the rejection.

6. Claims 1 and 2 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hoeprich (Hoeprich, Jr., P.D. et al., The Journal of Biological Chemistry, 254(32): 19086-19091, 1989; of record) in view of Gonzalez (Gonzalez et al. Scandinavian J. Immunol., 52: 113, August 2000).

As stated of record, Hoeprich does not teach or suggest a vaccine composition as currently claimed wherein said carrier protein is P64k as required by the claims.

The present application was filed on December 6, 2001 and claims priority to Cuban Application No. 286/2000, filed December 6, 2000 as evidenced by the filing receipt. The Gonzalez reference was published in August 2000 and, thus, is a § 102(a) publication date (i.e., less than a year prior to the effective filing date of the present application).

A § 102(a) publication can be overcome by a 37 CFR § 1.131 Affidavit to antedate the reference. *In re Foster*, 243 F.2d 980, 145 USPW 166 (CCPA 1965). Applicants submit herewith a 37 CFR § 1.131 Affidavit by inventor Belinda Sánchez Ramírez demonstrating that the fusion proteins as claimed were conceived and reduced to practice prior to the August 2000 publication date of the Gonzalez reference. Briefly, the TGFα-p64 fusion protein was generated using recombinant techniques known in the art prior to the August 2000 publication date of the Gonzalez reference.

Attached as Exhibit B of the declaration is a laboratory notebook page exemplifying the protocol used to generate P64-TGFα fusion protein as described in Examples 2 and 3 of the present application.

Briefly, the expression vector pM 92 was used. The plasmid contains the lpdA gene coding for P64k protein from Neisseria meningitidis (strain B385) under the control of E. coli tryptophan operon promoter (ptrp) and phage T4 transcriptional terminator (tT4). pM 92 contains ampicillin (Amp^R) and kanamycin (Km^R) antibiotic resistance expression cassettes. The pM92 vector was digested and subsequently ligated with the cDNA from TGFα.

The resulting plasmid codes for the fusion protein that contains hTGFα inserted among the amino acid 45/46 of P64k and containing a polyHis sequence.

FIG. 2 of the present application shows a schematic representation of the expression vector obtaining process. This vector codes for the fusion protein TGFα-P64K which was made using techniques described in the laboratory notebook page and herein.

In summary, the laboratory notebook page presented herein illustrates that the TGFα-P64K fusion protein compositions as presently claimed were conceived and reduced to practice prior to August 2000. Applicants respectfully request reconsideration and withdrawal of the rejection.

7. Claims 1, 4-6, 12 and 13 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hoeprich (Hoeprich, Jr., P.D. et al., The Journal of Biological Chemistry, 254(32): 19086-19091, 1989; of record) in view of Gonzalez (Gonzalez et al., Scandinavian J. Immunol., 52: 113, August 2000) and further in view of Gonzales (Gonzales et al., Vaccine Research, 6(2): 91-100, 1997; of record).

Hoeprich and Gonzalez (August 2000) have been addressed *supra*, and Applicants respectfully request reconsideration and withdrawal of the rejection.

8. Claims 1, 10 and 11 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hoeprich (Hoeprich, Jr., P.D. et al., The Journal of Biological Chemistry, 254(32): 19086-19091, 1989; of record) in view of Gonzalez (Gonzalez et al., Scandinavian J. Immunol., 52: 113, August 2000) and further in view of Gonzales-1997 (Gonzales et al., Vaccine Research, 6(2): 91-100, 1997; of record) or Gonzalez-1998 (Gonzales et al., Annals of Oncology, 9: 431-435, 1998; of record), and further in view of De Luca (De Luca et al., Oncogene, 19(51): 5863-5871, Nov. 2000).

Hoeprich and Gonzalez (August 2000) have been addressed *supra*.

The present application was filed on December 6, 2001 and claims priority to Cuban Application No. 286/2000, filed December 6, 2000 as evidenced by the filing receipt as discussed above. The De Luca reference was published in November 2000 and, thus, is a § 102(a) publication date (i.e., less than a year) prior to the effective filing date of the present application.

A 102(a) publication can be overcome by a 37 CFR § 1.131 Affidavit to antedate the reference. *In re Foster*, 243 F.2d 980, 145 USPW 166 (CCPA 1965). As discussed above, Applicants submit herewith a 37 CFR § 1.131 Affidavit by inventor Belinda Sánchez Ramírez demonstrating that the fusion proteins as claimed were conceived and reduced to practice prior to the November 2000 publication date of the De Luca reference.

Applicants respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

Applicants respectfully request prompt and favorable action with regard to pending claims 1, 2, 4-7 and 12-13. Further, Applicants respectfully request rejoinder and allowance of amended method claims 14-17.

If the Office determines that any additional fees are due, please charge Deposit Account No. 23-2415, referencing docket no. 30797-717.201.

If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (858) 350-2300.

Respectfully submitted,

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